PATENT
Attorney Docket No. 17591/2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Boyd

Application No. 09/427,873

Filed: October 27, 1999

Group Art Unit: 1645

Examiner: L. Lee

For: METHODS OF USING CYANOVIRINS TO INHIBIT VIRAL INFECTION

DECLARATION UNDER 37 C.F.R. § 1.132

1. I, Michael R. Boyd, am inventor of the subject matter disclosed and claimed in the above-identified patent application.

2. The data set forth below were generated under my direction.

3. Five groups of macaques, 13 animals in total, were used to test the efficiency of cyanovirin (CV-N) to inhibit viral infection. Three of the five groups (Groups I, II, and V, n=3 each) were intrarectally or intravaginally administered 1-2% CV-N microbicide gel. Two animals (Group III) were intrarectally administered a placebo gel which did not comprise CV-N. Approximately twenty minutes post-application, intrarectally or intravaginally, of the CV-N or placebo gel, all animals were intrarectally inoculated with 1ml of inoculant comprising 10^3 $TCID_{50}$/ml or intravaginally inoculated with 1 ml of inoculant comprising $5x10^3$ $TCID_{50}$/ml of SHIV89.6P virus, respectively. Two animals (Group IV) represented mock-treated, virus-infected controls. A dose of 10^3 $TCID_{50}$/ml or $5x10^3$ $TCID_{50}$/ml of SHIV89.6P

is known to produce 100% infectivity in macaques by intrarectal or intravaginal inoculation, respectively.

4. Clinical blood samples were drawn weekly and analyzed for virological, immunological and hematological evaluations. Following the first month, blood samples were taken every two weeks for two months. Four weeks post-inoculation with SHIV89.6P, no virus was isolated from experimental animals (Groups I, II, and V). Virus was isolated from control animals in Group III and Group IV. In addition to virus isolation as a means of identifying viral infection, PCR-based assays were performed to detect SHIV89.6P viral DNA in blood samples. No viral DNA was detected in blood samples taken from animals in Groups I, II, and V, while all control animals tested positive for viral DNA.

5. Peripheral blood monocytes (PBMC) were isolated from blood samples to identify infectious cells. In Group III and Group IV animals, infectious PBMCs were detected at week 1 post-inoculation through week 10 post-inoculation. No infectious PBMCs were detected in those macaques treated with CV-N gel. Likewise, no viral DNA was detected in PBMCs taken from CV-N-treated animals.

6. I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 1/23/01

Michael R. Boyd, M.D., Ph.D.